Remarks

Status of Claims:

Claims 1-20 are rejected. Claims 1, 2, 14, 17, and 18 are amended. Claims 1-20 remain pending.

The amendments are supported by the specification, claims, and figures as originally filed. No new matter is added. For instance, but without limitation, paragraph 0050 of the specification explains that the sample tube can be advanced into the cutter with the cutter fully advanced in the needle 104. Paragraph 0054 discloses an example of how the user may release the sample tube from the biopsy device when the desired number of samples have been taken. Support for the amendment to Claim 14 is found at paragraph 0057 on page 12 of the specification.

§ 102 Rejections:

Claims 1-13, 16-20 are rejected as anticipated by Burbank (US 5526822). Applicant respectfully traverses these rejections for at least the following reasons.

Claim 1 is amended to recite, among other things, a sample tube advancable within the hollow cutter when the distal end of the cutter is positioned within the biopsy needle, the sample tube having an open distal end sized for receiving a tissue sample severed by the cutter, the sample tube being releasably supported on the biopsy device such that the sample tube and at least one tissue sample stored therein may be removed from the biopsy device without disassembling the biopsy device

With respect to Claim 1, the Examiner states that Burbank's tubular knock out pin 92 is a sample tube. It is respectfully urged that this is not a correct characterization of the knock out pin 92 of Burbank, and that Burbank does not teach or suggest that knock out pin 92 serves or could serve as a sample tube for storing a tissue sample.

Burbank, at column 15 lines 12-20 teaches that the distal end of the knock out pin 92 serves to "stop" a tissue sample in a tissue containment chamber as the cutter 68 is withdrawn through the tissue containment chamber. Accordingly, Burbank does not teach that knock out pin 92 is a sample tube as recited in Claim 1. Instead, Burbank teaches that the tissue sample does not enter

the distal end of the knock out pin 92, but rather is "stopped" by the distal end of the knock pin to be positioned in the containment chamber.

In an alternative embodiment described at column 17, lines 24-51, Burbank describes a biopsy device that has a piercing needle 244 disposed within an outer cutter 268, and a tubular knock out pin 292 movably positioned within the needle 244. Burbank also discloses that in this embodiment the end of the knock out pin 292 can be open and the tissue sample can be suctioned through the interior of the knock out pin into a tissue sample receiving area. This embodiment also does not anticipate Claim 1 for at least the following reasons.

First, the embodiment of Burbank employing the knock out pin 292 has a piercing needle disposed within an outer cutter, in contrast to Claim 1, which recites a hollow biopsy needle having a tissue receiving port and a hollow cutter advancable within the biopsy needle to sever tissue received within the tissue receiving port.

Second, the knock out pin 292 does not provide a tissue sample tube that is releasably supported on a biopsy device such that the sample tube and at least one tissue sample stored therein may be removed from the biopsy device without disassembling the biopsy device, as recited in amended Claim 1. Burbank teaches that a tissue sample can be suctioned through the interior of the knock out pin 292 to a tissue sample receiving area. Even if one were to attempt to construe the knock out pin 292 to be a "sample tube", this construction would still not teach or suggest the subject matter of amended claim 1 because it is respectfully urged that Burbank does not teach or suggest that the knock out pin 292 is releasably supported to permit the knock out pin with a tissue sample to be removed from the biopsy device. Instead, Burbank has the tissue sample placed in a tissue sample receiving area (column 17, line 51).

Claims 2:

Amended Claim 2 recites the sample tube is adapted to store multiple tissue samples in an end to end configuration. Figure 7 of the present application illustrates tissue samples stored in an end to end configuration in a sample tube. It is respectfully urged that Burbank does not teach or

suggest a sample tube adapted to store multiple tissue samples in an end to end configuration, or stacking multiple tissue samples in an end to end configuration within a sample tube.

Claim 4-6

With respect to Claims 4-6 the Examiner states:

> In regards to Claims 4-6, Burbank et al disclose the sample tube (92) advanced by a pneumatic cylinder (Col.14, line 40-43).

It is respectfully urged this rejection is improper in that the knock out pin (92) of Burbank is not properly characterized as a "sample tube" for all the reasons set forth above, and so does not disclose a sample tube advanced by fluid pressure, pneumatic pressure, or associated with a pneumatic cylinder.

Claim 16:

The examiner rejects Claim 16 stating that Burbank discloses a "sample tube" 92 that is releasably supported in a biopsy device, and that Burbank discloses a "rotatably driven component" for advancing and rotating the cutter in the form of a collet 762. It is respectfully urged that this rejection is improper for at least the following reasons.

First, it is respectfully urged this rejection is improper in that the knock out pin (92) of Burbank is not properly characterized as a "sample tube" for all the reasons set forth above.

Second, it is respectfully urged that the Examiner has mischaracterized the collet 762 as being rotatably driven. Burbank discloses that collet 762 is mounted in support 764 (see column 19, lines 50-58). It is respectfully urged that Burbank fails to disclose that collet 762 or support 764 is rotatably driven.

Instead, it would appear from the disclosure of Burbank cited by the Examiner that the collet 762 is stationary, and that a drive motor 780 rotates cutter 768 (see column 19, lines 65-column 20, lines 8 of Burbank). The Examiner is respectfully requested to explain how Burbank teaches or implies that collet 762 is rotatably driven, or withdraw the rejection.

Claim 17

Amended Claim 17 recites, among other things, advancing a hollow sample tube in the cutter with the distal end of the hollow cutter disposed in a needle, to position the tissue sample in the sample tube, and removing the sample tube from the hollow cutter with at least one tissue sample positioned within the sample tube.

Withdrawal of the Examiner's rejection of Claim 17 (and all dependent claims) is requested for at least the following reasons.

The Examiner states that Burbank discloses a hollow sample tube 578. In fact, Burbank at column 19, lines 5-24 discloses a first cutter 568 and a second cutter 578. Accordingly, Burbank does not teach a "sample tube 568", or a sample tube that is removed from a cutter with at least one tissue sample positioned within the sample tube.

The Examiner also states that "sample tube 568" includes a "sample cassette (40)". It is respectfully urged that Burbank does not teach or suggest that the second cutter 578 "includes a sample cassette 40". The Examiner is respectfully requested to point out the specific Figure and/or column and line number in Burbank that teaches that the second cutter 578 of Burbank "includes a sample cassette".

Claim 18:

Amended Claim 18 recites stacking multiple samples within the sample tube in an end to end configuration.

It is respectfully urged that Burbank does not teach or suggest stacking multiple samples in an end to end configuration within the sample tube. The Examiner is respectfully requested to point out what portion of Burbank teaches such a method, or withdraw the rejection. The Examiner is also respectfully requested to consider that Figure 8 (referred to by the Examiner) does not appear to show tissue samples stacked in an end to end configuration within a sample tube.

§ 103 Rejections:

Claims 11-12 and 14-15 are rejected as obvious. These rejections are traversed for the reasons set forth above with respect to the base claims, and also for the following additional reasons.

Under MPEP 2143, in order to establish a *prima facie* case of obviousness, the prior art reference or combination of references must teach or suggest all of the limitations of a claim. A *prima facie* case of obviousness also requires that there be some teaching suggestion, or motivation to modify the references either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. MPEP 2143.01. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.

With respect to Claims 11 and 12, the Examiner admits that Burbank does not disclose a sample tube comprising a tube wall feature for retaining tissue samples. However, the Examiner states that Burbank discloses "modifying components of the biopsy device, such as said hollow cutter (68) to include a notch or 'tissue receiving port' to retain tissue, best seen in Figure 12A or 14A."

It is respectfully urged that even if Burbank teaches "modifying" a cutter, as the Examiner suggests, such a teaching does not teach suggest a sample tube, or a sample tube having a wall feature as claimed.

Claims 14-15:

Claims 14 and 15 are rejected as obvious over Burbank in view of Tsonton (2004/0077972). This rejection is respectfully traversed for all the reasons set forth with respect to the base claims, and for at least the following additional reasons.

MPEP 2143 explains that the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. Actual evidence of a suggestion, teaching, or motivation to combine prior art references must be shown. *In re Dembiczack*, 50 USPQ2d 1614 (Fed. Cir. 1999).

It is respectfully urged that in the pending Office Action, the Office has purported to address this issue by invoking stock language from the MPEP regarding hindsight reasoning, but the Office has still failed to provide the evidence of a motivation to combine or modify.

In particular, the Examiner has merely selectively picked certain features in Burbank and certain features in Tsonton, and then, without providing any evidence of motivation, concluded that one would combine these selected features. Because the evidence of motivation required by MPEP 2143.01 is lacking, Applicant respectfully requests that the rejection be withdrawn.

Further, it is respectfully urged that one would not be motivated to make the combination recited by the Examiner. The Examiner refers to an "obturator stylet" in Tsonton, which is slid into a cutter lumen to close a cutter port, and that the stylet may have radially oriented holes near its distal end to maintain fluid communication between the vacuum chamber and the cutter lumen.

It is respectfully urged that a teaching by Tsonton to place radial holes in an obturator stylet does not provide any teaching or suggestion with respect to providing holes through a portion of a cutter. This rejection is based on improper hindsight reliance on the Applicant's disclosure, and also ignores that Tsonton places radial holes in a component other than the cutter. Accordingly, it is respectfully urged that Tsonton actually teaches away from the modification proposed by the Examiner.

Based on the foregoing, all pending claims are in a condition for allowance. Accordingly, Applicant respectfully requests reconsideration and an early notice of allowance.

Respectfully submitted,

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